

MAR 23 2010

**510(K) SUMMARY  
OF SAFETY AND EFFECTIVENESS**

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the G-FORCE® Ti Suture Anchor System.

Submitted By:	Wright Medical Technology, Inc.
Date:	February 22, 2010
Contact Person:	Kellen Hills
Proprietary Name:	Regulatory Affairs Specialist
Common Name:	<b>G-FORCE® Ti Suture Anchor System</b>
Classification Name and Reference:	Soft Tissue Anchor
Device Product Code and Panel Code:	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener - Class II
Predicate Device:	Orthopedics/87/MBI/HWC
	ANCHORLOK® Soft Tissue Anchor System (K971282)

**DEVICE INFORMATION****A. DEVICE DESCRIPTION**

The G-FORCE® Ti Suture Anchor System is a sterile, single-use, hand-held device intended to aid in the attachment of soft tissue to bone. The G-FORCE® Ti Suture Anchor System comes preloaded with non-absorbable polyethylene-based sutures, needles and titanium alloy anchors. The anchors are available in a variety of sizes with correspondingly sized suture.

**B. INTENDED USE**

The G-FORCE® Suture Anchor System is indicated for use:

- In the repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;
- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;

- In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments.

### **C. SUBSTANTIAL EQUIVALENCE INFORMATION**

The indications for use of the G-FORCE® Ti Suture Anchor System are limited in scope when compared to the predicate. The technological characteristics by which the intended use is achieved is the same for both the subject and predicate systems.

The safety and effectiveness of the G-FORCE® Ti Suture Anchor System are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this 510(k).

### **D. PERFORMANCE DATA**

Bench testing was used to demonstrate that the torque and tensile strength characteristics of the G-FORCE® Ti Suture Anchor System are safe and effective.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.  
% Ms. Kellen Hills  
Regulatory Affairs Specialist  
5677 Airline Road  
Arlington, Tennessee 38002

MAR 23 2010

Re: K100579

Trade/Device Name: G-FORCE® Ti Suture Anchor System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: MBI, HWC  
Dated: February 23, 2010  
Received: March 2, 2010

Dear Ms. Hills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

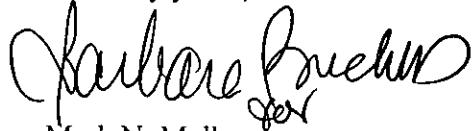
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K100579

Device Name: G-FORCE® Suture Anchor System

### Indications For Use:

The G-FORCE® Suture Anchor System is indicated for use:

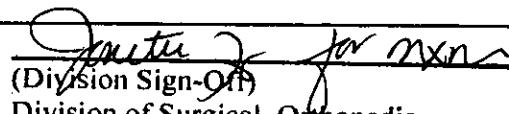
- In the repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;
- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments.

Prescription Use xxx  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K100579

Concurrence of CDRH, Office of Device Evaluation (ODE)